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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/009,802	01/20/98	MCCARTHY S	MEI-008-1

000959
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HM12/0928

EXAMINER
YUCEL, I

ART UNIT	PAPER NUMBER
1636	6

DATE MAILED: 09/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

please see attached

Office Action Summary

Application No.	Applicant(s)
09/009,802	McCarthy
Examiner	**Group Art Unit**
Remy Yucel	1636

☒ Responsive to communication(s) filed on *Oct 9, 1998*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-60* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-60* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to comply ..... SEQUENCE DISCLOSURES + Error Report

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 1-60 are pending in the application.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures and the Raw Sequence Listing Error Report.

Since the response appears to be **bona fide**, but through an apparent oversight or inadvertence failed to provide a complete response, applicant is required to complete the response within a time limit of one (1) month from the date of this letter, 37 CFR 1.135(c).

NO EXTENSION OF THIS TIME LIMIT MAY BE GRANTED UNDER EITHER 37 C.F.R. 1.136(a) OR (b), BUT THE STATUTORY PERIOD FOR RESPONSE SET FOR THIS COMMUNICATION MAILED MAY BE EXTENDED UP TO A MAXIMUM OF SIX (6) MONTHS UNDER 37 CFR 1.136.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to nucleic acids, vectors, host cells and methods of producing CRSP protein, classifiable in class 536, subclass 23.1 and class 435, subclasses 325 and 69.1.

II. Claims 18 and 19, drawn to a transgenic animal comprising a transgene encoding CRSP, classifiable in class 800, subclass 8.

III. Claims 20-31, drawn to isolated CRSP proteins and fusion proteins, classifiable in class 530, subclass 350.

IV. Claims 32-34, drawn to antibodies which specifically bind CRSP, classifiable in class 424, subclass 130.

V. Claim 38, drawn to a method of modulating a cell-associated activity by stimulating CRSP protein activity or expression classifiable in class 435, subclass 4.

VI. Claim 40, drawn to a method of modulating a cell-associated activity by inhibiting CRSP protein activity or expression, using anti-sense, classifiable in class 536, subclass 24.5.

VII. Claim 41, drawn to a method of modulating a cell-associated activity by inhibiting CRSP protein activity or expression, using an antibody, classifiable in class 424, subclass 130.

VIII. Claim 44, drawn to a method of treating a subject with a small molecule, classifiable in class 514, subclass 1.

IX. Claim 45, drawn to a method of treating a subject with a protein, classifiable in class 514, subclass 2.

X. Claim 46, drawn to a method of treating a subject with a nucleic acid, classifiable in class 514, subclass 44.

XI. Claims 50, 51 and 55, drawn to method of detecting for the presence of CRSP activity using nucleic acid, classifiable in class 435, subclass 6.

XII. Claims 52, 53 and 56, drawn to method of detecting for the presence of CRSP activity using antibodies, classifiable in class 435, subclass 7.1.

XIII. Claim 59, drawn to an assay for detecting a genetic alteration in a cell, classifiable in class 435, subclass 6.

XIV. Claim 60, drawn to an assay for detecting a genetic alteration in a cell, classifiable in class 435, subclass 91.

Claims 37 and 42 are generic to groups V, VI and VII.

Claim 39 is generic to groups VI and VII.

Claims 43, 47 and 48 are generic to groups VIII, IX and X.

Claims 49, 54, and 57 are generic to groups XI and XII.

Claim 58 is generic to groups XIII and XIV.

Election of any one of the groups listed immediately above will result in examination of the corresponding generic claim(s).

The inventions are distinct, each from the other because of the following reasons:

Inventions of groups I-IV are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different groups are drawn to chemically and biologically distinct products which are not disclosed as capable of use together. For example, the nucleic acids of group I are distinct from proteins and antibodies and transgenic animals of groups II-IV.

Inventions V-XIV are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different groups are drawn to distinct methods that do not contain the same steps, the methods are not disclosed as capable of use together and the methods all have different functions. For example, the method of claim V is a method of modulating a cell-associated activity by stimulating CRSP protein activity or expression; whereas the methods of groups VI and VII are drawn to methods of modulating a cell-associated activity by inhibiting CRSP protein activity or expression by using chemically distinct products, specifically, antisense nucleic acids and antibodies. Groups VIII-X are drawn to methods of treating an individual and have different functions and effects from the methods of V-VII. Groups XI and XII are drawn to methods of detecting CRSP protein activity in a biological sample and have different functions and effects from methods of modulating a cellular activity (V-VII) and methods of treating an individual (VIII-X). Finally, groups XIII and

XIV are drawn to diagnostic methods to detect a genetic alteration and have different functions and effects from methods of modulating a cellular activity (V-VII), methods of treating an individual (VIII-X) and methods of detecting CRSP protein activity in a biological sample (XI and XII).

The product of group I may be used in the distinct methods of groups V, VI, X, XI, XIII and XIV. The product of group II is not disclosed as capable of use with any of the methods of groups V-XIV. The product of group III may be used in the distinct methods of groups VIII and IX and the product of group IV may be used in the distinct methods of groups VII and XII. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the same product may be used in materially different processes such as methods of modulating a cellular activity and methods of diagnosing a genetic alteration (both are performed with the product of group I). Conversely, a method for modulating a cellular activity may be performed with antisense molecules (group I) or with an antibody or a protein (groups IV and III, respectively). Thus, the instant inventions are distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by

their different classification and because the searches required for the groups are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6 (d)). The Group 1600 FAX numbers are (703) 308-4242 or (703) 305-3014. Unofficial faxes may be sent to the examiner at (703) 305-7939. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Remy Yucel, Ph. D. whose telephone number is (703) 305-1998. The examiner can normally be reached on Monday through Fridays from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott can be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

REMY YUCEL, PH.D
PATENT EXAMINER

Remy Yucel, Ph. D.
September 27, 1999